constantly at corresponding points. Specific changes to the skin temperature indicate the existence of mammary carcinomas.

A second group of thermographic methods include those using plate thermography, such as in the apparatus disclosed by German Patent D.E. 83 26 341 U1. A thermographic plate is pressed onto the female breast, and as a function of temperature, a thermographic coating on the plate assumes different colors. This method renders patterns of vessels optically visible in a thermographic manner, with certain vessel patterns revealing higher levels of heat than other areas. Specific structures or features indicate abnormal changes. The actual diagnostic method of plate thermography is described in greater detail in "Atlas der Plattenthermographie" by G. Lauth and G. Mühlberger. This atlas gives an introduction to physicians inexperienced in plate thermography. However, plate thermography is limited in that successful use requires an experienced and skilled physician. The technique is prone to high rates of error, especially when utilized by an inexperienced physician.

SUMMARY

In accordance with the invention, an apparatus facilitates diagnosis of pathological changes in the female breast using the surprising discovery that, by cooling a thermooptical foil for predetermined duration and then illuminating and recording a thermooptical image of the foil, it is possible to standardize thermooptical images to similar and reproducible recording conditions to permit easy and more reliable diagnosis of pathological changes.

The invention records a thermooptical image of the female breast using a thermooptical foil positioned on a frame, the foil being cooled to a standardized and constant temperature. The thermooptical foil is positioned adjacent a casing that is opaque except for the side facing the breast, and a cooling box is positioned between the casing and foil. The foil is also positioned to contact the breast, and a timer measures a presettable amount of time that passes after the cooling box begins to cool the foil. The cooling box causes a constant temperature to be established throughout the thermooptical foil, allowing for standardized and reproducible recording conditions. An illuminating system illuminates the thermooptical foil from within the casing and a digital camera is used to record image data from the illuminated foil for evaluation and diagnosis. A triggering

mechanism is used to operate the digital camera so that the camera makes its photographic recording of the breast at the end of the presettable amount of time that passes after the cooling box begins to cool the foil.

To effect cooling of the thermooptical foil, the cooling box can use a cooling medium fluid such as water supplied by a cooling medium circuit. The cooling medium circuit includes a cooling medium inlet and a cooling medium outlet, with an adjustable thermostat being used to measure the amount of cooling performed and being responsive to the temperature of the cooling medium. The cooling box can be transparent and an antireflection disk can also be positioned between the cooling box and digital camera.

The foil can have an initial position in which it is not in contact with the cooling box. Pins, springs, or other devices can be included to permit surface contact between the foil and cooling box, and a locking device can be included to fix the foil in place after making contact with the cooling box. A clamping device can also be included in the apparatus for clamping the breast against the foil. In some embodiments, a pad can be used in the clamping device to press the breast against the foil and can be variably spaced from the foil.

In some embodiments, the casing, cooling box, and foil can all be mounted on a multi-articulation arm to permit positioning of apparatus components with respect to the patient being examined. The multi-articulation arm can be mounted on an instrument trolley to permit easy handling of the casing and easy transportation of the apparatus.

Some embodiments of the invention include a monitor screen connected to the digital camera to permit the observation of images as they are viewed through the camera. A computer and keyboard can also be included to operate the triggering mechanism and manipulate image data recorded by the digital camera. Various other types of output devices, such as printers and various facilities for storing digital images recorded by the camera, such as diskette and CD-ROM devices, can also be included.

In some embodiments, image evaluating devices connected to the digital camera can permit automatic evaluation of information contained in the recorded image for the existence of a pathological change or for features characteristic of mammary carcinomas. An image evaluating device can also be configured to compare recorded images with earlier images of the same breast or with reference images. In some embodiments, the

monitor screen can be subdivided into two windows, one window being used for displaying the present image and the other window being used for displaying an earlier image of the same breast or a reference image.

Those skilled in the art will realize that this invention is capable of embodiments which are different from those shown in that the details of the structure of the recording apparatus disclosed herein can be changed in various manners without departing from the scope of this invention. Accordingly, the drawings and description are to be regarded as illustrative in nature and are not to restrict the scope of the invention. Additionally, the claims are to be regarded as including such equivalent recording apparatuses as do not depart from the nature and scope of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding and appreciation of this invention and many of its advantages, reference will be made to the following Detailed Description of the Preferred Embodiments taken in conjunction with the accompanying drawings:

FIG. 1 is a diagrammatic side view of part of one embodiment of an apparatus for recording a thermooptical image of the female breast according to the invention;

FIG. 2 is another part of the apparatus of FIG. 1; and

FIG. 3 diagrammatically represents the combined apparatus including the components depicted in FIGS. 1 and 2 as used on a patient.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings, identical reference numerals and letters designate the same or corresponding parts throughout the several figures shown in the drawings.

FIG. 1 diagrammatically depicts a side view of part of a special embodiment of the apparatus according to the invention. The apparatus comprises a casing **4** which, for standardizing the thermooptical images, is opaque except on the side facing the breast where a frame **9** is mounted. This configuration permits image recording to be free from external reflections. A film or thermooptical foil **1** is positioned on the frame **9**. A cooler or transparent cooling box **7** and an antireflection disk **6** are placed between the foil **1** and casing

4, with the antireflection disk 6 being placed closer toward the interior of the casing 4 and forming the interior wall of the cooling box 7. The foil 1 can be stretched over the narrow frame 9 and be biased to a relaxed state position (as shown in FIG. 1) that is two to three centimeters in front of a front wall 8 of the cooling box 7. The quadrangular frame 9 is held in the four corners of the casing 4 by steel pins 10 and the spacing of the foil 1 from the front wall of the cooling box 7 is maintained by four springs 11. The springs 11 are inverted over the pins 10 and in the relaxed state are sufficiently long to hold the foil 1 at the relaxed state position away from the front wall 8 of the cooling box 7. The springs 11 and frame 9 are configured so that sufficient spacing exists between the foil 1 and casing 4 to permit adjustments and corrections to the position of the foil 1 after the breast is placed against the foil 1 without creating surface contact between the foil 1 and the front wall 8 of the cooling box 7.

The cooling box 7 has a cooling medium inlet 12a and a cooling medium outlet 12b connecting the cooling box 7 in a circuit with a thermostat 17 by means of hose lines 12c (cf. FIG. 2). The cooling medium can be a fluid such as water. Continuous water circulation through the cooling medium inlet 12a and cooling medium outlet 12b and constant water temperature ensure the constancy of the temperature of the foil 1. Based on the thermal sensitivity of the foil 1, the set cooling should always be constant. Some embodiments of the invention can allow the operator of the apparatus to perform manual, computer-controlled adjustment of the degree of cooling by the cooling medium, the operator issuing control commands to a computer 3 (cf. FIG. 2) through keyboard 13 (cf. FIG. 2).

A digital camera 2 is positioned inside the casing 4, the digital camera 2 being positioned to record images in the direction of the frame 9. An illuminating system comprises two lamps 5 for illuminating the foil 1, the lamps 5 of the illuminating system being oriented to optimize the recordings of the digital camera 2. In addition, the illumination provided by the lamps 5 contributes to the creation of standardized recording conditions.

A clamping mechanism that includes a pad **14** and mounting support **15** is mounted on the apparatus to gently clamp the breast against the foil **1**. As shown in FIG. 1, the mounting support **15** defines a horizontal plane in which the spacing between the pad **14** and foil **1** can be varied by moving the pad **14** along the horizontal plane toward and away from the foil **1**. Varying the spacing between the pad **14** and foil **1** enables the breast to be pressed gently but firmly against the foil **1** which further assists in the creation of standardized recording conditions.

FIG. 2 diagrammatically depicts another part of the apparatus of FIG. 1. A thermostat **17**, a computer **3** with a keyboard **13** and a screen **16** are located in an instrument trolley **19**. Referring briefly to FIG. 3, a multi-articulation arm **18** is mounted on the trolley **19**, the multi-articulation arm **18** supporting the casing **4** and being extendable to orient the casing **4** into various mobile positions. Some embodiments permit the multi-articulation arm **18** to be locked in order to orient the casing in a fixed position relative to the patient. The multi-articulation arm **18** can also be hollow in order to accommodate power, communication, hosing, and other supply lines to the digital camera **2**, cooling box **7**, and components of the illuminating system **5**.

Referring now to FIG. 3, the connected casing **4** and trolley **19** are represented, the cooling box **7**, foil **1**, and pad **14** being depicted in an exploded view with the foil **1** being rotated approximately 90° for the purpose of further functional description. The placement of the thermooptical foil **1** on the female breast results in a heat pattern, represented by different colors corresponding to the areal thermal states of the skin, to appear on the foil **1**. This thermal pattern is reversible after the foil **1** has been removed from the breast. Cooling the foil **1** has the effect of minimizing coloration of the foil **1**, with color patterns becoming more sharply contoured and with contrast to the black background being improved. Cooling the foil has the added effect of reducing the effect that surface or "skin heat" has on the foil coloration, the foil coloration instead displaying and representing peaks of heat dissipated from more low-lying heat sources deep beneath the surface of the breast.

In the operation of the recording apparatus, recording positions correspond to those for mammography, but with the difference that in the case of breasts of normal size, two lateral and two craniocaudal exposures are made for each breast. The reason for this difference is that in "vascugraphy" emitted heat is measured and greater accuracy can be obtained in results by measuring from both sides. After the breast and foil 1 come into contact, the breast is held with the soft pad **14** which the patient can position herself. This is advantageous in that it tends to avoid discomfort associated with the squeezing examination that patients often experience during mammography.

The duration of time in which the foil is cooled is also significant and must be defined and measured in order to establish standardized recording conditions during the cooling process. For example, cooling time can be measured from the instant when the foil **1** is gently pressed counter to the tension of springs **10** on a cooling box **7** and when a locking means (not shown) snaps into a locked position accordingly. At that time, a timing system (not shown) begins to measure the amount of time that passes as the cooling process continues. At the end of a presettable amount of time, the timing system operates a triggering mechanism (not shown) which is used to operate the digital camera **2** to shoot or record the image on the thermooptical foil **1**. After completion of the image recording, the pad **14** can be returned to its initial, pre-clamping position to release pressure against the breast. In some embodiments, the releasing action can be provided mechanically with a gas spring pressure mechanism (not shown) incorporated into the mounting support **15**. Recording conditions can therefore be standardized by reproducing conditions or "settings" such as the cooling temperature and duration of the cooling period.

During recording or shooting of the thermooptical image by the digital camera **2**, all settings can be monitored on the monitor screen **16**. The monitor screen further displays all image data being recorded by the digital camera **2**. The dimensions of the foil **1** correspond to those of a mammographic film with a size, for example, of 18 x 24 centimeters. On replacing the foil **1** by a finished mammographic image (e.g. a positive case) and homogeneous transillumination of the film from the outside in the direction of the digital camera **2**, it is possible to obtain a simple, inexpensive form of digitized storage of the mammogram for the particular

patient. The congruent superimposing of the thermal image and the mammogram on the screen can provide valuable information to the diagnosing doctor. The thermooptical image recorded by the digital camera **2** can then be transferred to the computer **3**, where an image evaluation facility can perform an automatic evaluation of the image by utilizing appropriate software. Other types of output devices for storing digital images recorded by the digital camera **16** are also contemplated to be within the scope of the invention and include but are not limited to printed output devices, diskettes, and CD-ROM devices.

The invention can allow for automatic or electronic interpretation of thermooptical images without necessarily requiring the interpretation skills of an examining physician. Pathological changes can be detected by comparing the thermographically obtained vascular pattern and shape of the patient's vessels with reference data, as is particularly appropriate during the initial examinations of a particular patient. However, if previous recordings or exposures exist, it is also possible to carry out a comparison of the current recorded image with one or more images recorded previously. The invention may include a facility for displaying a current recorded image next to a previous recorded image in a split-window fashion. Changes in the thermooptical image may indicate changes in the vascular pattern of the breast which in turn may indicate a pathological change warranting further investigation with another more intrusive diagnostic technique such as a biopsy.

Many other modifications and changes can be made to the recording device of this invention by those skilled in the art without departing from the spirit and scope of this invention. Thus, the claims when appended are intended to be interpreted to cover such equivalent recording apparatuses as do not depart from the spirit and scope of this invention.

In the Claims

Please cancel claims 1-16 and add the following claims:

17. An apparatus for recording a thermooptical image of a female breast on a thermooptical foil comprising: